CVS EXTRA STRENGTH ITCH RELIEF- diphenhydramine hydrochloride and zinc acetate spray CVS Pharmacy

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

Active ingredient

Purpose

Uses

Temporarily relieves itching and pain associated with minor irritations, burns, scrapes, cuts, insect bites and rashes due to poison ivy, poison oak and poison sumac. Dries the oozing and weeping of poison ivy, poison oak and poison sumac.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses

Temporarily relieves itching and pain associated with minor irritations, burns, scrapes, cuts, insect bites and rashes due to poison ivy, poison oak and poison sumac. Dries the oozing and weeping of poison ivy, poison oak and poison sumac.

Warnings

For external use only. Flammable. keep away from fire or flame.

Do not use - with any other product containing diphenhydramine, even one taken by mouth. - On large areas of the body

Ask a doctor before use - on chicken pox - on measles

When using this product avoid contact with the eyes

Stop use and ask a doctor if condition worsens or does not improve within 7 days. - symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- do not use more than directed
- **Adults and children 2 years and older:** apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age: consult a doctor

Other information

Store at 20 degrees to 25 degrees C (68 degrees to 77 degrees F)

Inactive Ingredients

purified water, SD alcohol 40-B, glycerin, povidone, tromethamine

TEAR HERE



Compare to the active ingredients in Benadryl®Spray*



EXTRA STRENGTH

TOPICAL ANALGESIC • SKIN PROTECTANT

Relieves: Itching & pain associated with insect bites & rashes due to poison ivy, oak & sumac

For topical use only 2 FL OZ (59 mL)

L248CVS20Z-1





Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
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*This product is not manufactured or distributed by McNeil-PPC, Inc., owner of the registered trademark Benadryl[®]. R248CVS20Z-1

Drug Facts DO NOT USE IF SAFETY SEAL LABEL IS TORN OR MISSING

Active ingredients

Purpose

Diphenhydramine HCl 2% ... Topical analgesic Zinc acetate 0.1% Skin protectant

Drug Facts (continued)

TEAR HERE

Uses temporarily relieves itching and pain associated with minor irritations, burns, scrapes, cuts, insect bites and rashes due to poison ivy, poison oak, and poison sumac. Dries the oozing and weeping of poison ivy, poison oak & poison sumac.

Warnings For external use only. Flammable. Keep away from fire or flame.

Do not use ■ with any other product containing diphenhydramine, even one taken by mouth ■ on large areas of the body

Ask a doctor before use ■ on chicken pox ■ on measles

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or does not improve within 7 days ■ symptoms
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Inactive ingredients purified water, SD alcohol 40-B, glycerin, povidone, tromethamine

CVS EXTRA STRENGTH ITCH RELIEF

diphenhydramine hydrochloride and zinc acetate spray

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-248

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	20 mg in 1 mL	
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
PO VIDO NE (UNII: FZ989 GH94E)	
TROMETHAMINE (UNII: 023C2WHX2V)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:59779-248-25	59 mL in 1 BOTTLE, SPRAY		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part336	08/10/2011		

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 4/2012 CVS Pharmacy